

PHARMACY DISPENSING PATTERNS, COST AND HEALTHCARE UTILIZATION: A STUDY OF LANSOPRAZOLE

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In the Department of Veterans Affairs (VA) expenditures for pharmaceuticals were nearly \$2Billion or 11% of the total budget in FY1999 (October 1998–September 1999), and have been increasing from 11 to 21 percent annually.

OBJECTIVE: To develop methods to examine pharmacy dispensing patterns and to determine the association with healthcare costs and utilization.

METHODS: 24,765 patients who received a prescription of Lansoprazole during FY1999 at any of the 10 hospitals one regional network were studied. Dispensing patterns leading to overlaps (overfilling) and gaps (underuse), defined as a dispensing at least 10 days before or after, respectively, the days supply of the prior dispensing ended, were identified. Outpatient visit and hospitalization rates were calculated for 6 months of follow-up and tested for associations with overfilling and underuse. Source of dispensing, Mail (M) or Window (W), and days of supply were examined to gain insight into factors that contribute to inefficient dispensing patterns.

RESULTS: 49.7% of all patients experienced an overlap, 51.1% experienced a gap, and 27.2% experienced both. The net cost associated with overfilling for 6 months of follow-up was \$392,616, or 7.9% of the total 6-month cost of approximately \$5Million for Lansoprazole. Gaps and overlaps in medications were associated with higher utilization of both inpatient and outpatient services. A mix of MW dispensing pairs more often resulted in gaps or overlaps than concordant pairs (MM or WW). 10.7% of dispensings were for days supply of 31-to-90 days; however, 49.2% of 31-to-90 day prescriptions resulted in overlaps.

CONCLUSION: Overfilling is estimated to be 8% of total costs for Lansoprazole, and is associated with increased utilization. Further research is needed to determine how pharmacy dispensing patterns impact healthcare costs and outcomes. With increasing pharmaceutical costs and emphasis on patient safety, research into efficient delivery and timely receipt of medication is important.

GASTROINTESTINAL DISEASES/DISORDERS— Quality of Life Presentations

EFFECT OF RABEPRAZOLE ON HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN PATIENTS REPORTING INEFFECTIVE RELIEF WITH PRIOR OMEPRAZOLE OR LANSOPRAZOLE THERAPY

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OBJECTIVES: The purpose of this study is to evaluate the effect of rabeprazole (RAB) 20mg daily on HRQoL among patients that participated in the Future of Acid Suppression Therapy (F.A.S.T.) trial. The F.A.S.T. trial was an open-label, multicenter, 8-week study measuring the effectiveness of RAB in 2579 patients with erosive gastroesophageal reflux disease (GERD). The two sub-populations in this analysis were patients reporting prior ineffective relief with omeprazole (OME) (n = 290) or lansoprazole (LAN) (n = 212) within 3 months of study entry.

METHODS: The SF-36 health survey was used to measure HRQoL in patients at baseline and after 8 weeks of treatment with RAB. The SF-36 includes eight scales: Physical Functioning (PF), Role-Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role-Emotional (RE) and Mental Health (MH). Two summary measures, Physical Health Component Summary (PCS) and Mental Health Component Summary (MCS), are produced from aggregating the most highly related scales. This study used paired t-tests to compare baseline to 8-week scores for significant changes in HRQoL.

RESULTS: There were 248 OME and 180 LAN patients that completed a SF-36 survey at baseline and 8-weeks. All scales and summary scores in both groups had a statistically significant ($p < 0.05$) mean increase after 8 weeks of treatment on RAB except for PF in patients having prior ineffective OME therapy. For both groups, the following scales had a increase in score of greater than five points from baseline to 8-weeks which is considered clinically significant: RP, BP, VT, SF, and RE. In addition the group of patients having prior ineffective OME therapy also had a clinically significant increase in MH.

CONCLUSIONS: Overall, RAB showed significant improvements in HRQoL among patients with erosive GERD who reported ineffective relief with prior OME or LAN therapy.

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FACTOR STRUCTURE AND FURTHER VALIDATION OF THE GASTROESOPHAGEAL REFLUX DISEASE (GERD) SYMPTOM ASSESSMENT SCALE

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OBJECTIVES: The GERD Symptom Assessment Scale (GSAS) measures distress associated with 15 GERD-related symptoms. The purpose of this study was to evaluate its factor structure.

METHODS: The GSAS was collected at baseline and four weeks following treatment in two randomized, placebo-controlled trials of rabeprazole for moderately severe GERD. Patients rated how distressed they were by each symptom from 0 (no symptom or not at all distressed) to

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3 (very distressed). We conducted a principal components analysis (PCA) of baseline responses. Overall and subscale scores were computed as average distress scores across relevant symptoms. We assessed internal consistency reliability using Cronbach's alpha. We assessed reproducibility by evaluating the intraclass correlation coefficient (ICC) between baseline and follow-up scores among patients reporting no change in overall symptom severity ($n = 45$). We compared mean GSAS scores across subgroups of patients with varying levels of symptom severity at baseline and varying degrees of heartburn relief at follow-up using t -tests.

RESULTS: The mean (sd) age of the 278 patients was 43.6 (11.9) years, and most were female (65%) and Caucasian (77%). The PCA and reliability estimates suggested three subscales: gastrointestinal symptoms (GI), regurgitation and heartburn (RHB), and upper respiratory manifestations (URM). The subscale and overall scores were reliable (Cronbach's alpha, ICC): GI = 0.81, 0.81; RHB = 0.79, 0.80; URM = 0.73, 0.72; Overall = 0.87, 0.85. Mean baseline overall and subscale scores were at least 10% poorer among patients reporting greater symptom severity ($p < 0.01$). Patients reporting complete heartburn relief at follow-up reported 13% to 16% greater improvements in overall, GI, and RHB scores than patients who did not experience complete relief ($p < 0.001$).

CONCLUSIONS: This study confirmed the reliability and validity of the overall GSAS score. Further, researchers may want to consider analyzing the GI, URM, and RHB subscale scores as secondary indicators of symptom distress.

GASTROINTESTINAL DISEASES/DISORDERS— Health Policy Presentations

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USE OF NONSTEROIDAL ANTI-INFLAMMATORY AGENTS IN PATIENTS AT HIGH RISK FOR GASTROINTESTINAL SIDE EFFECTS IN A VETERANS AFFAIRS MEDICAL CENTER

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The risk of significant injury to the gastrointestinal (GI) tract from nonsteroidal anti-inflammatory drugs (NSAIDs) has been well established. Patients concurrently using warfarin or who have had a prior serious hospital GI event are considered to be at high risk. In 2000, the Veterans Affairs (VA) implemented treatment criteria for the use of NSAIDs including cyclooxygenase-2 (COX-2) inhibitors. The high-risk criteria-based therapy is sal-salate, non-selective NSAID plus a proton pump inhibitor (PPI), high-dose famotidine, or misoprostol or a COX-2 inhibitor.

OBJECTIVES: The purpose of this study was to assess the level of criteria-based NSAID prescribing in high risk patients at the New Mexico VA Healthcare System.

METHODS: Patients with concurrent prescriptions for an NSAID and warfarin or previous hospital GI event were identified utilizing VA databases. Current therapy was compared to criteria-based therapy to assess level of implementation.

RESULTS: Out of 7,625 NSAID users, 184 patients were identified: concurrent warfarin ($n = 98$), prior hospital GI event ($n = 84$), and concurrent warfarin with a previous hospital GI event ($n = 2$). Fifty-eight percent were over the age of 65. The NSAIDs prescribed were ibuprofen (42.4%), naproxen (20.1%), etodolac (16.8%), indomethacin (8.2%), salsalate (5.4%), piroxicam (3.3%), COX-2 inhibitors (2.1%), and sulindac (1.6%). Criteria-based therapy was prescribed for 22% of patients. Only 12% of warfarin patients and 33% of previous hospital GI event patients were prescribed criteria-based therapy. Of the patients prescribed a non-selective NSAID ($n = 139$), there were only 19% prescribed a criteria-based GI protective medication.

CONCLUSIONS: In this study, few patients, at high-risk for GI complications due to NSAIDs, received criteria-based therapy.

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ASSESSMENT OF USE OF THE VETERANS AFFAIRS' CRITERIA FOR NONSTEROIDAL ANTI-INFLAMMATORY AGENTS

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The risk of significant injury to the gastrointestinal (GI) tract from nonsteroidal anti-inflammatory drugs (NSAIDs) has been well established. The Veterans' Affairs (VA) implemented treatment criteria for the use of NSAIDs including the new class of drugs, cyclooxygenase-2 (COX-2) inhibitors. These criteria utilize a self-administered Gastrointestinal Risk Assessment Tool (GI Score), developed from the Arthritis, Rheumatism, and Aging Medical Information System (ARAMIS) database, to assess risk. This tool generates a composite score used to predict the 1-year risk level, level 1 (no risk) to level 4 (substantial risk), for the potential of an NSAID-associated GI event.

OBJECTIVES: The purpose of this study was to assess the risk level and the level of implementation of the VA criteria.

METHODS: The GI score was used to assess the patient's risk level calculated on the basis of data from VA demographic, prescription, hospitalization, clinic visits, and active problem lists databases. Current therapy was compared to criteria-based therapy to assess level of implementation.

RESULTS: There were 7,625 NSAID users in the New Mexico VA Healthcare System: 86 previous hospitalized GI event patients, 100 concurrent warfarin therapy patients, 223 corticosteroid therapy patients, and 205 rheumatoid arthritis patients. Thirty-six percent of the VA patients were over the age of 65. The most commonly